510(k) Summary

JUL 27 2007

1. Contact Information

Submitter: NovoSci, Inc.
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Contact Person: David Makanani

Date Prepared: 4/13/2007

2. Device Names

Trade: *Joline D-Line Catheter ST* family of catheters in kits consisting of
- Dual Lumen Short Term Hemodialysis Catheter
- Extra Flow (EF) Short Term Hemodialysis Catheter

Common Name: Hemodialysis Short Term Catheter

Classification Name: 78 MPB – Catheter, Hemodialysis, Non-implanted
21 CFR 876.5540 (b)(2)

3. Predicate Device

Kendall Mahurkar Catheter, K963446
Kendall Mahurkar QPlus Catheter, K030209
Medcomp Duo-flow Catheter, K974236

4. Description of Device

The *Joline D-Line Catheter ST* family of catheters, consisting of the Dual Lumen Short Term Hemodialysis and Extra Flow (EF) Short Term Hemodialysis catheters are a polyurethane radiopaque catheter which allows for hemodialysis, hemoperfusion and apheresis. A cross-sectional view of the shaft of the *Joline D-Line Catheter ST* catheters reveals a double "D" configuration -one "D" for the arterial lumen and the other for the venous lumen. In the Extra Flow (EF) Short Term design the venous lumen extends beyond the arterial lumen and terminates in a round tip. The Dual Lumen Short Term catheter has both lumens exiting together and incorporates side-holes along the shaft of the catheter body in its design.

Two color-coded safety clamps, red and blue, identify arterial and venous extensions. Important information such as priming volume and catheter length is printed on both sides of the clamp. A swiveling suture ring is available to secure the catheter after placement.

Two extensions merge into a tapered bifurcation joint or hub molded to the catheter body. These extensions can be straight, curved or curved-to-one-side.

The finished kit consists of either the Dual Lumen Short Term Hemodialysis or Extra Flow (EF) Short Term Hemodialysis catheters packaged with various accessory components. These components include: guidewire, introducer needle, dilator, and luer lock caps. Labeling includes instructions for use for the various accessories, where appropriate.

5. Indications for Use

The Dual Lumen Short Term Hemodialysis and Extra Flow (EF) Short Term Hemodialysis catheters are indicated for use in hemodialysis, hemoperfusion and apheresis for short-term duration of less than 30 days via the subclavian, femoral or jugular vein.

6. Comparison to Predicate Device

The Dual Lumen Short Term Hemodialysis and Extra Flow (EF) Short Term Hemodialysis catheters are substantially equivalent to the Kendall Tyco Mahurkar, Kendall Tyco Mahurkar QPlus, and the Medcomp Duo-Flow Catheters.

A close examination of specifications reveals that there are no major differences in design, materials, performance, biocompatibility, safety and product effectiveness. Supporting information in the form of engineering bench testing has been provided.

7. Non-clinical Performance Tests:

Engineering studies were performed to FDA's "Guidance on Premarket Notification 510(k) Submissions for Short Term and Long Term Intravascular Catheters", and "Coronary and Cerebrovascular Guidewire Guidance", ISO 10555 – International standard for "Sterile, Single-Use, Intravascular Catheters, ISO 10993 – International standard for "Biological Evaluation of Medical Devices", and additional test requirements for hemodialysis catheters.

8. Conclusion

The Dual Lumen Short Term Hemodialysis and Extra Flow (EF) Short Term Hemodialysis catheters were demonstrated to be substantially equivalent to the predicate devices based on its design, test results, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2007

Mr. David Makanani
Vice President
NovoSci™
2828 North Crescent Ridge Drive
THE WOODLANDS TX 77381

Re: K063355
Trade/Device Name: Joline D-Line Catheter ST family of catheters consisting of the
- Dual Lumen Short Term Hemodialysis catheter
- Extra Flow (EF) Short Term Hemodialysis catheter

Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MPB
Dated: July 20, 2007
Received: July 23, 2007

Dear Mr. Makanani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for NCB

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063355

Device Name: The *Joline D-Line Catheter ST* family of catheters consisting of the

- Dual Lumen Short Term Hemodialysis catheter
- Extra Flow (EF) Short Term Hemodialysis catheter

Indications for Use:

The Dual Lumen Short Term Hemodialysis and Extra Flow (EF) Short Term Hemodialysis catheters are indicated for use in hemodialysis, hemoperfusion and apheresis for short-term duration of less than 30 days via the subclavian, femoral or jugular vein.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K063355